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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
GABEL, GAILENE	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 05/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/846,346	JACKOWSKI ET AL.	
	Examiner	Art Unit	
	Gailene R. Gabel	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 February 2005 and 24 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 36-43* is/are pending in the application.

4a) Of the above claim(s) *1 and 41-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *36-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1 and 36-43* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/24/05 has been entered.

Amendment Entry

2. Applicant's amendment and response filed 2/14/05 is acknowledged and has been entered. Claims 1, 36, 41, and 42 have been amended. Claims 1 and 41-43 remain withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being claims drawn to a non-elected invention. Currently, claims 1 and 36-43 are pending. Claims 36-40 are under examination.

3. Applicant requests rejoinder of claim 1 with the group of claims under prosecution on the premise that claims 36-40 were amended to recite an "isolated biopolymer marker" just as claim 1 is also amended to recite same. Applicant specifically argues that a search for amended claims 36-40 would encompass the search for this specific biopolymer marker that is recited in claim 1.

Applicant's argument is not persuasive because restriction requirements are set forth for reasons of patentable distinction between each independent invention and Inventions I and II having been rendered independent and distinct and related as product and process of use wherein the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the isolated biopolymer marker of Invention I can be incorporated into a biosensor for use in protein binding kinetic studies. The record set forth in the previous restriction requirement clearly indicated that the delineated inventions are in fact patentably distinct each from the other or independent from the other. The requirement is still deemed proper and is therefore made FINAL for reasons of record.

Accordingly, claims 1 and 36-43 are pending. Claims 36-40 are under examination.

Specification

4. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: "wherein the presence of isolated biopolymer marker having SEQ ID NO. 1 is indicative of a link to Type II diabetes."

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 36-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 36, preamble is vague and indefinite in relation to step a) in reciting, "determining the presence of an isolated biopolymer marker having SEQ ID NO. 1" because it is unclear how a biopolymer marker can be [present] in isolated form and obtained in isolated form from a patient. Perhaps, Applicant intends, "determining the presence of a biopolymer marker having SEQ ID NO. 1".

Claim 36, step b) is ambiguous in reciting, "conducting mass spectrometric analysis on ... peptide fragments obtained therein" because it is unclear how individual peptide fragments are obtained from a patient sample since proteins or biopolymer markers are manifested as full length proteins in native form. Please clarify.

Claim 36, step b) is confusing and lacks clear antecedent support in reciting, "and comparing mass spectrum profiles of *said isolated biopolymer marker* having SEQ ID No. 1 to mass spectrum profiles *of peptide fragments* obtained and analyzed from said sample" because it appears that there is only 1 element (the sample) being compared to itself, i.e. 1) said biopolymer marker [*antecedent basis is* from the patient sample] and 2) peptide fragments from said sample. Perhaps, claim 36, step b) should recite, "and comparing mass spectrum profiles of an isolated biopolymer marker having SEQ ID NO. 1 and a molecular weight of 1998 daltons in a control sample to mass spectrum profiles of said peptide fragments obtained and analyzed from said patient

sample". "An isolated biopolymer marker having SEQ ID NO. 1 and a molecular weight of 1998 daltons" defines that a control is being compared to the patient sample.

Claim 36, step c) is confusing and lacks clear antecedent support in reciting, "confirming the presence of *said isolated biopolymer marker* having SEQ ID No. 1" because it is unclear how a biopolymer marker can be present in isolated form and obtained in isolated form from a patient. Alternatively, it is unclear what element in step b), i.e. control sample or patient sample, the recitation of "*said isolated biopolymer marker having SEQ ID No. 1"* intends to refer back to.

Claim 36, in the last 2 lines of the claim, is vague and lacks clear antecedent support in reciting, "the presence of *said isolated biopolymer marker*" because it is unclear how a biopolymer marker can be present in isolated form and obtained in isolated form from a patient. Alternatively, it is unclear what element in steps b) and c), i.e. control sample or patient sample, the recitation of "*said isolated biopolymer marker having SEQ ID No. 1"* intends to refer back to.

New Matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 36-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

In this case, the specification does not appear to provide literal or adequate descriptive support for the recitation of "biopolymer marker having SEQ ID NO: 1 is indicative of a link to Type II diabetes". Applicant's disclosure at page 27, last full paragraph to page 28, only provides that the biopolymer marker having SEQ ID NO: 1 is indicative of an individual suffering from Type II diabetes, but provides no specific showing of its specific link to the disease, how it is linked to the disease, or what aspect of the disease the marker is intended to be linked to. Additionally, none of the originally filed claims recited the limitation in question. Recitation of claim limitation lacking literal support in the specification or originally filed claims constitutes new matter.

Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 36-40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

As set forth in *In re Wands, 858 F .2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988)*, enablement requires that the specification teach those skilled in the art to make and use

the invention without undue experimentation. Factors to be considered in determining, whether a disclosure would require undue experimentation include 1) the nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the quantity of experimentation necessary, 7) the relative skill of those in the art, and 8) the breadth of the claims.

The nature of the invention- the invention is directed to a method for determining the presence of a biopolymer marker having SEQ ID NO. 1 in a patient sample... wherein the presence the biopolymer marker having SEQ ID NO. 1 is indicative of Type II diabetes. The method is performed by obtaining a sample from a patient, conducting mass spectrometric analysis on the sample, and comparing the mass spectrum profile of the sample with the mass spectrum profile of an isolated biopolymer marker having SEQ ID NO: 1 and a molecular weight of 1998 daltons in a control sample, wherein the presence a biopolymer marker having SEQ ID NO. 1, a molecular weight of 1998 daltons in the patient sample, and displaying a peak mass spectrum profile as that of the isolated biopolymer marker in the control sample, provides an indication of a link to Type II diabetes.

The state of the prior art- the prior art of record fails to disclose a method for determining the presence of a biopolymer marker having SEQ ID NO. 1 in a patient sample, wherein the presence the biopolymer marker having SEQ ID NO. 1 is indicative of a link to Type II diabetes.

The predictability or lack thereof in the art- there is no predictability based on the instant specification that the claimed method which shows determination of the presence of a biopolymer marker having SEQ ID NO: 1, provides and supports an indication of a link to Type II diabetes.

The amount of direction or guidance present- the specification fails to provide guidance to enable the use of an isolated biopolymer marker having SEQ ID NO: 1, to indicate a link to Type II diabetes.

The presence or absence of working examples- there are no working examples that show data and results wherein determination of the presence of an isolated biopolymer marker having SEQ ID NO. 1, specifically supports an indication of a link to Type II diabetes. Figure 1 shows a limited pool of 7 Type II diabetes patients expressing the biopolymer marker having SEQ ID NO: 1 where in Figure 2, displays a characteristic mass spectrum profile which peaks at 1998 daltons; however, nowhere in the specification provides data that shows that there is a nexus connecting the biopolymer marker having SEQ ID NO. 1 and exhibiting a mass spectrum profile that displays a peak at 1998 daltons, with indication of a link to Type II diabetes.

The quantity of experimentation necessary- it would require undue amount of experimentation for the skilled artisan to make and use the method as claimed based on the instant specification.

The relative skill of those in the art-the level of skill in the art is high.

The breadth of the claims- as recited, the instant claims are directed to a method for determining the presence of a biopolymer marker having SEQ ID NO. 1 in a patient sample... wherein the presence the biopolymer marker having SEQ ID NO. 1 is indicative of a link to Type II diabetes. The method is performed by obtaining a sample from a patient, conducting mass spectrometric analysis on the sample, and comparing the mass spectrum profile of the sample with the mass spectrum profile of an isolated biopolymer marker having SEQ ID NO: 1 and a molecular weight of 1998 daltons in a control sample, wherein the presence a biopolymer marker having SEQ ID NO. 1, a molecular weight of 1998 daltons in the patient sample, and displaying a peak mass spectrum profile as that of the isolated biopolymer marker in the control sample, provides an indication of a link to Type II diabetes.

In page 12, lines 1-17 of the specification, Applicant generally discusses SELDI-MS and time-of-flight (TOF) detection procedures which are used to maximize the diversity of biopolymers which are verifiable within a particular sample for analysis of their ability to enable diagnosis of a disease state relative to the presence or absence of the biopolymer marker. Pages 12-16 of the specification provides numerous biopolymer markers associated with diseases of the complement system, i.e. the major effector of the humoral branch of the immune system (C3 deficiency- recurrent bacterial infection and autoimmune reactions, etc.), and the Syndrome X continuum, i.e. multifaceted syndrome (insulin resistance/hyperinsulinemia, dyslipidemia, hypertension, obesity, glucose intolerance, non-insulin dependent diabetes mellitus, etc). In page 27, line 17 to page 28, line 2, Applicant provides that a specific disease marker which is SEQ ID

NO. 1 having a molecular weight of about 1998 daltons, characterized as a C3f fragment from the complement system, has been isolated and identified as having a characteristic profile set forth in Figure 2. Applicant points to Figure 1 and notes that from the data set forth therein, one can conclusively deduce that the marker which is SEQ ID NO. 1 provides indication of an individual suffering from Type II diabetes. However, the data set in Figure 1 only consists of an assay pool of 7 Type II diabetes patients who exhibit the presence of the claimed marker. Nowhere in the limited disclosure provides a description of how and why the biopolymer marker having SEQ ID NO. 1 is conclusively a biopolymer marker indicative of a link to Type II diabetes based on its manifestation in relation to the characterization of the disease. Nowhere in the specification provides adequate description and data that support the assertion that a biopolymer marker having SEQ ID NO: 1 is specifically indicative of a link to Type II diabetes. There is no evidentiary showing, given the instant specification and Figures 1 and 2, that one skilled in the art would have deduced that the claimed biopolymer marker is a reactive marker that provides indication of a link to Type II diabetes, because a population of 7 subjects is not a significant assay pool to draw one to such conclusion. Additionally, the 7 subjects in Figure 1 from whom the samples were obtained appear to be known Type II diabetes patients; hence, there is no representation of previously unknown subjects that would have been rendered as having Type II diabetes using the instant biopolymer marker having SEQ ID NO. 1. There are also no working examples that would lead one skilled in the art to arrive to conclusion that the biopolymer marker having SEQ ID NO: 1 in the specification is a

specific marker for indication of a link to Type II diabetes. Alternatively, Capiaumont et al. is prior art that teaches that the biopolymer marker having SEQ ID NO: 1 (C3f or SSKITHRIHWESASLLR), is a fragment of human complement containing HWESAS motif which exhibits an indication of chronic renal failure, without specific reference to, relation with, or link to Type II diabetes. For the specification to be enabled, there needs to be evidentiary showing that upon determination of the presence of the biopolymer marker protein having SEQ ID NO. 1 and molecular weight of 1998 daltons in any given population, a specific indication of a link to Type II diabetes can be confirmed. The teaching of Capiaumont et al. does not appear to support such deduction because SEQ ID NO. 1 appears to indicate chronic renal failure, as well. Additionally, the 7 subjects listed in Figure 1 who positively exhibited the claimed biopolymer protein are patients known to be symptomatic of Type II diabetes so that a determination of the presence of the biopolymer marker protein having SEQ ID NO. 1 and molecular weight of 1998 daltons in a large assay population, might selectively and exclusively point to an indication of chronic renal failure instead, as taught in the Capiaumont et al. reference, absent occurrence of Type II diabetes.

In view of the teachings of In re Wands, 8 USPQ2d 1400, it has been determined that the level of experimentation required to enable the breadth of the claims is undue. It has been set forth above that 1) the experimentation required to enable an indication of a link to Type II diabetes using the biopolymer marker having SEQ ID NO: 1, would be great as 2) there is no experimental evidence provided that would indicate that the claimed method would work to indicate a link to Type II diabetes, using the biopolymer

marker having SEQ ID NO: 1; 3) there is no adequate guidance that shows that the claimed method can be used to exclusively indicate a link to Type II Diabetes using the biopolymer marker having SEQ ID NO: 1 that is isolated and identified, 4) the nature of the invention is a method for determining the presence of a biopolymer marker having SEQ ID NO. 1 in a patient sample... wherein the presence the biopolymer marker having SEQ ID NO. 1 is indicative of Type II diabetes; the method is performed by obtaining a sample from a patient, conducting mass spectrometric analysis on the sample, and comparing the mass spectrum profile of the sample with the mass spectrum profile of an isolated biopolymer marker having SEQ ID NO: 1 and a molecular weight of 1998 daltons in a control sample, wherein the presence a biopolymer marker having SEQ ID NO. 1, a molecular weight of 1998 daltons in the patient sample, and displaying a peak mass spectrum profile as that of the isolated biopolymer marker in the control sample, provides an indication of a link to Type II diabetes, 5) the relative skill of those in the art is high, yet 6) the state of the prior art has been shown to be unpredictable as evidenced by the fact that no prior art has been cited that shows the claimed biopolymer marker having SEQ ID NO. 1, provides specific indication of a link to Type II diabetes, and lastly 7) the claims broadly recite a method for determining the presence of a biopolymer marker having SEQ ID NO. 1 in a patient sample... wherein the presence the biopolymer marker having SEQ ID NO. 1 is indicative of a link to Type II diabetes; the method is performed by obtaining a sample from a patient, conducting mass spectrometric analysis on the sample, and comparing the mass spectrum profile of the sample with the mass spectrum profile of an isolated

biopolymer marker having SEQ ID NO: 1 and a molecular weight of 1998 daltons in a control sample, wherein the presence a biopolymer marker having SEQ ID NO. 1, a molecular weight of 1998 daltons in the patient sample, and displaying a peak mass spectrum profile as that of the isolated biopolymer marker in the control sample, provides an indication of a link to Type II diabetes.

Therefore, it is maintained that one of ordinary skill in the art could not make and use the invention as claimed without undue experimentation.

Response to Arguments

8. Applicant's arguments filed 2/14/05 have been fully considered but they are not persuasive.

A) Applicant amended the claims so as to recite that the presence of an isolated biopolymer marker having SEQ ID NO: 1 in a patient sample that is displaying a peak profile at 1998 daltons in a mass spectrum is indicative of a link to Type II diabetes, and contends that the term "link" which refers to a condition of *being associated with or connected to* is fully supported by the specification because in page 17, lines 11-14, it is indicated that an objective of the invention is to evaluate samples containing a plurality of biopolymers for the presence of disease specific marker sequences which evidence a link to at least one specific disease state and that Figure 1 supports the association of the claimed peptide with Type II diabetes.

In response, the recitation of "presence of a biopolymer marker having SEQ ID No. 1 ... a link to Type II diabetes" is not adequately supported by the specification

because there is no basis for how and why a biopolymer marker having SEQ ID NO. 1 and molecular weight of 1998 should be linked to Type II diabetes. Figure 1 shows statistical data from an assay pool of 7 patients manifesting the claimed protein and who have been determined to have Type II diabetes and Figure 2 only shows a spike of the claimed protein at 1998 daltons. Accordingly, nowhere in the disclosure has shown the nexus between the claimed biopolymer marker and its link to Type II diabetes.

B) Applicant argues that a test for enablement indicate that if statement of utility in the specification contains within it a connotation of *how to use*, then 35 USC 112 is satisfied. Applicant contends that the mere fact that something has not previously been done clearly is not in itself, a sufficient basis for enablement rejection.

Contrary to Applicant argument, the provision of 35 U.S.C. 112, first paragraph, requires that Applicant's disclosure shall contain *a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same* and shall set forth the best mode contemplated by the inventor of carrying out his invention. In the instant case, Applicant has not shown how to make the invention by providing a basis for confirming a nexus between the biopolymer marker having SEQ ID NO. 1 which displays a peak at 1998 daltons, and Type II diabetes. An assay pool of 7 patients known to have Type II diabetes and exhibiting the presence of the claimed protein is hardly a basis for determining an indication of a link between the protein and Type II diabetes. There is

no other evidentiary showing provided in the instant specification, that one skilled in the art would have deduced that the claimed protein is a biopolymer marker that is indicative of a link to Type II diabetes, because a population of 7 subjects is not a significant assay pool to draw one to such conclusion. As discussed supra and having considered all the Wands factors, it has been determined, that making and using the invention would require undue experimentation in the part of a skilled artisan.

C) Applicant argues that the Examiner is incorrect in asserting that there is a limited assay pool of 7 patient who exhibit the presence of the claimed marker and contends that the data actually was obtained from a large assay pool of over 500 patients. According to Applicant, Figure 1 only displays the data which is relevant to the claimed biopolymer marker in the application and its link to Type II diabetes. Applicant attempts to establish this point by providing Appendix A which applicant contends, illustrates the link between the claimed biopolymer marker and Type II diabetes.

In response, Appendix A shows a list of 500 patients suffering from a variety of diseases such as stroke, congestive heart failure, myocardial infarction, and Type II diabetes and individually lists the protein names, sequences, and molecular weights of the different biopolymer markers that are manifested by them. However, Appendix A and Figure 1 still fail to establish how Applicant arrived to the relevancy of the biopolymer marker having SEQ ID NO. 1 and molecular weight of 1998 daltons to an indication of a link to Type II diabetes, as opposed to the numerous other diseases. There is no evidentiary presentation of how a such a nexus would have been

established between the positive identification of the claimed protein, its molecular weight, and the alleged occurrence of an indication of a link to Type II diabetes patient.

D) Applicant argues that the Capiaumont et al. reference is not relevant to the claimed invention because the claims do not include or exclude the possibility of renal failure or any other condition in patients in which the claimed peptide is positively identified.

In response, Applicant's argument is not on point because the Capiaumont et al. reference is not relied upon in the context of an art rejection whereupon a teaching within the reference reads on the claimed invention. The pending enablement rejection utilizes the teaching of Capiaumont et al. to support Examiner's grounds for rejection that a positive identification of the biopolymer marker having SEQ ID NO. 1 and molecular weight of 1998 daltons does not definitively provide an indication of a link to Type II diabetes, absent evidentiary showing 1) that a large population of Type II diabetes patients manifest the claimed protein, 2) of a nexus that confirms the relevancy of the claimed protein to the indication of a link to Type II diabetes, and 3) that the 7 patients listed in Figure 1 were manifesting the claimed protein as a result exclusively of Type II diabetes, absent an occurrence of chronic renal failure. Given the teaching of Capiaumont et al., there is reason to believe that the claimed protein manifested in any one of the 7 patients may have resulted from an occurrence of chronic renal failure alone, and not necessarily from Type II diabetes.

Response to Declaration

9. Applicant provides a Declaration under 37 CFR 132 to support that Appendix A was originally filed in Applicant's ASN 09/846,330, which is now US 2002/0160420. According to Applicant, the data from a clinical trial involving over 500 patients, clarifies the identification of SEQ ID NO. 1 in serum samples of patients suffering from a variety of disease states as being evidentiary of Type II diabetes.

In response, Appendix A does not appear to have provided evidentiary showing that a population of previously unknown subjects can be specifically identified as having an indication of a link to Type II diabetes using the claimed method and biopolymer marker having SEQ ID NO. 1, which is recited in the rejected claims. Appendix A shows a list of 500 patients suffering from a variety of diseases such as stroke, congestive heart failure, myocardial infarction, and Type II diabetes and individually lists the protein names, sequences, and molecular weights of the different biopolymer markers that are manifested by them. However, Appendix A and Figure 1 still fail to establish how Applicant arrived to the relevancy of the biopolymer marker having SEQ ID NO. 1 and molecular weight of 1998 daltons to an indication of a link to Type II diabetes, as opposed to the numerous other diseases. Applicant has not presented how a such a nexus would have been established between the positive identification of the claimed protein, its molecular weight, and the alleged occurrence of an indication of a link to Type II diabetes patient. Additionally, prior art (Capiaumont et al.) shows that the claimed biopolymer marker is also exhibited in patients having chronic renal failure.

10. No claims are allowed.

11. THIS **ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (571) 272-0820. The examiner can normally be reached on Monday, Tuesday, and Thursday, 7:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

10. No claims are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (571) 272-0820. The examiner can normally be reached on Monday, Tuesday, and Thursday, 7:00 AM to 4:30 PM.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gailene R. Gabel
Patent Examiner
Art Unit 1641
May 6, 2005

Christopher L. Chin

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641
5/13/05